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10/519,024	11/30/2005	Benny Pesach	227/04279	3303

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PRTSI
P.O. Box 16446
Arlington, VA 22215

EXAMINER	
ELHASSAN, AHMED A	
ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,024	PESACH ET AL.	
	Examiner	Art Unit	
	AHMED ELHASSAN	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/22/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/27/06, 11/15/06, 08/06/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 12, 13, 14, 17, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagar et al (WO 0215776) in view of Seip et al. article (Noninvasive Estimation of Tissue Temperature Response to Heating Fields Using Diagnostic Ultrasound, IEEE Transactions on Biomedical Engineering , Vol. 42, No. 8 Aug.1995).

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Regarding claim 1, Nagar includes a tissue viability monitor (FIG. 1 & 6) for determining viability of a biological tissue (via determination of the concentration of a substance within the tissue; pp. 1, lines 1-3) comprising:

at least one light source (pp. 2, line 32) controllable to illuminate the tissue with light that is absorbed by an analyte in the tissue to generate photoacoustic waves therein (pp. 3, line 16);

at least one acoustic transducer ("ultrasound sensor", pp. 2, line 29) that generates signals responsive to the photoacoustic waves;

means for generating (pp. 2, line 32) a temperature difference between temperature of the tissue and an ambient temperature of surrounding tissue (pp. 22, lines 19-20) ; and

a controller (pp. 30, line 24) adapted to control the means for generating a temperature difference in the tissue and to control the light source to illuminate the tissue with light absorbed by at least one analyte ("blood", pp. 3, line 24) in the tissue and wherein the controller processes the signals generated by the at least one transducer to determine concentration of at least one analyte in the tissue (pp. 18, lines 1-7) and to determine temperature in the tissue (included in determination that "'bolus' cools downs to a temperature substantially equal to the ambient temperature", pp. 23, lines 26-27) and therefrom a relaxation time during which the temperature

difference relaxes to zero ("cools down to ambient temperature", pp. 23, line 26) and uses the concentration and relaxation time to provide a measure of viability (relaxation time is also a function of ambient temperature which can be the patient's core temperature; a common indicator of viability).

Nagar lacks explicitly stating that the ultrasound signals are processed to determine tissue temperature.

Seip teaches using ultrasound to monitor tissue temperature (abs., line 1) to provide non-invasive treatment feedback when using ultrasound as a therapeutic agent (pp. 828, right column, 3rd paragraph lines 2 and 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nagar with using ultrasound signals to determine temperature of the tissue, in order to provide non-invasive treatment feedback when using ultrasound as a therapeutic agent.

Regarding claim 2, Nagar- Seip as applied to claim 1, includes a tissue viability monitor wherein the controller processes the signals to determine locations of sources of the photoacoustic waves within the tissue (Nagar; pp. 3, line 17).

Regarding claims 3-5, Nagar- Seip as applied to claim 2, includes a tissue viability monitor

wherein the locations of sources of photoacoustic waves are determined with a resolution equal to or better than about 20 micrometers (Nagar; pp. 12, lines 11-12 teach a one wavelength resolution at a frequency equal to, or greater than 10 MHz, pp. 16, line 14, at 100MHz, for example, one wavelength is about 15 micrometer)

Regarding claim 6, Nagar- Seip as applied to claim 1, includes a tissue viability monitor wherein the at least one analyte is a plurality of analytes (Nagar; "blood", pp, 2, line 24, contains different analytes e.g. plasma, hemoglobin, oxygen, nitric oxide etc).

Regarding claim 12, Nagar- Seip r as applied to claim 1 includes that the controller (No. 30, FIG. 1) determines temperature of the tissue (Nagar; "cools down to a temperature substantially equal to ambient temperature", pp. 23, lines 26-27) during generation of the temperature difference (Nagar; "between light pulses", pp. 23, line 26) to monitor the generation of the temperature difference (Nagar; via the pulse train pp. 23, line 25).

Regarding claim 13, Nagar- Seip as applied to claim 12, includes that the controller (Nagar; No. 30, FIG. 1) controls the means for generating a temperature difference responsive to the determined temperature (Nagar; by varying the pulse width & duration; pp. 23, lines 25-26).

Regarding claim 17, other than the transmitting transducer (also included in Nagar; No. 26, FIG. 5A), rest of claim limitations have been addressed in the Nagar- Seip rejection of claim 1, above.

Regarding claim 18, Nagar- Seip as applied to claim 17, includes that the characteristic is a frequency shift of the scattered acoustic waves relative to a fundamental acoustic frequency of the structure of the tissue (pp. 10, line 22).

Regarding claim 19, the method set forth is included in the operation of Nagar- Seip system as addressed in the rejection in of claim 1 above.

Regarding claim 14, Nagar as applied to claim1, includes that to determine a relaxation time, the light source illuminates the tissue with light at a wavelength at which light is absorbed by water to generate photoacoustic waves in the tissue.

Nagar lacks that the controller determines the relaxation time via signals generated by the at least one transducer used to determine temperature of water in the tissue and thereby of the tissue.

Seip teaches using ultrasound to monitor tissue temperature (abs., line 1) by determining temperature of water in the tissue and thereby of the tissue (pp. 829, paragraph. 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nagar with using ultrasound to monitor tissue temperature by determining temperature of water in the tissue and thereby of the tissue, in order to provide non-invasive treatment feedback when using ultrasound as a therapeutic agent (pp. 828, right column, 3rd paragraph lines 2 and 5).

2. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagar et al (WO 0215776) in view of Seip, as applied to claim 1, further in view of Ward et al (US 7113814).

Regarding claims 7- 10, Nagar as applied to claim 1, includes that the tissue viability monitor analyzes a substance in the body (pp.1, line 4).

However, Nagar as applied to claim 1 lacks that the substances comprises cytochrome c a, a3, Hydrogen ions and hemoglobin.

Ward teaches a spectroscopic method wherein cytochrome, Hydrogen ions and hemoglobin are measured (col. 23, lines 55-62) in order to detect shock and determine effective treatments (abs. line 14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nagar with measuring the patient's cytochrome, Hydrogen ions and hemoglobin, in view of Ward, with the motivation to detect shock and determine effective treatments

3. Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagar et al (WO 0215776) in view of Seip, as applied to claim 1, and further in view of Mourad (US 6875176).

Regarding claim 11, Nagar tissue viability monitor as applied to claim 1, lacks that the means for generating a temperature difference comprises an acoustic transducer, which the controller controls to transmit acoustic waves, to the tissue, that generate the temperature difference.

Mourad teaches an acoustic transducer, which a controller controls to transmit acoustic waves, to the tissue, that generate the temperature difference (FIG. 2 & col. 12, line 16) in order to diagnose and monitor diseases characterized by physical changes in tissue properties (abs. , lines 15-16).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nagar with an acoustic transducer, which the controller controls to transmit acoustic waves, to the tissue, that generate the temperature difference, in view of

Mourad, with the motivation to diagnose and monitor diseases characterized by physical changes in tissue properties

Regarding claim 20, the method set forth is included in the operation of Nagar-Mourad system as addressed in the rejection of claim 11 above.

4. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagar in view of Seip, as applied to claim 1, further in view of Unger (US 6627421).

Regarding claim 15, Nagar as applied to claim 1, lacks a catheter having a probe end that is positioned in a neighborhood of or in contact with the tissue wherein the light source comprises an optic fiber having an optic end located at the probe end from which optic end light that illuminates the tissue is radiated.

Unger teaches catheter (col. 13, line 52) having a probe end that is positioned in a neighborhood of or in contact with the tissue wherein the light source (col. 3, line 10) comprises an optic fiber having an optic end located at the probe (FIG. 2B) end from which optic end light that illuminates the tissue is radiated, in order to elicit formation of pores (col. 3, line 6) to facilitate localized drug delivery ("chemotherapy", col. 18, line 26).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nagar with a catheter having a light source at its tip with the motivation to further use the same probe also to elicit formation of pores to facilitate localized drug delivery.

Regarding claim16, Nagar-Unger as applied to claim15 includes an acoustic transducer mounted in the probe end of the catheter (col.3, line 12 & co. 18, lines 36-37).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AHMED ELHASSAN whose telephone number is (571)270-7390. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

/AHMED ELHASSAN/
Examiner, Art Unit 3768